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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/725,962	12/02/2003	Samuel M. Owens	ABGENIX.071A	3958

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/725,962	OWENS ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *4,5 and 16-19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-15,20 and 21* is/are rejected.

7)☒ Claim(s) *22-23* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 5/30/06, is acknowledged.

Claims 1-2 have been amended.
Claims 22-23 have been added.
Claims 1-23 are pending.

2. Applicant's election without traverse of group I, drawn to antibodies specific for amphetamine, claims 1-3, 6-15, and 20-21 in the reply filed on 5/30/06 is acknowledged. Furthermore, applicant has elected SEQ ID NO: 5 and SEQ ID NO: 23 as the species of heavy and light chain respectively. It is noted that all of the claimed heavy and light chain SEQ ID NOS: are free of the art and have been rejoined.

Claims 16-19 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-3, 6-15, and 20-23 read on the elected invention and are being acted upon.

3. The use trademarks has been noted in this application (e.g. XENOMOUSE™ on page 30). Each letter of the trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

4. Claims 22-23 are objected to for being dependent upon a rejected base claim.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the limitation "said monoclonal antibody" in line 1-2. There is insufficient antecedent basis for this limitation in the claim or in independent claim 1.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-2, 6-15, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, there is insufficient written description to demonstrate that applicant was in possession of the claimed genus of antibodies that bind to a "drug of abuse".

The instant claims are drawn to antibodies that bind to a "drug of abuse". The instant specification on pg. 7 discloses that a "drug of abuse" refers to chemical agents which are either ingested or otherwise consumed by an individual and which may induce adverse health consequences. Therefore, the tern "drug of abuse" encompasses a wide range of structurally different drugs. For example, "drugs of abuse" might reasonably encompass chemotherapeutic agents, nicotine, or even alcohol. The term might even encompass insect poison or bleach which is accidentally ingested. In contrast to the broad genus of drugs encompassed by "drugs of abuse", the instant specification only discloses generating antibodies using amphetamine, methamphetamine and phencyclidine. Thus, one of skill in the art would conclude that the specification fails to provide adequate written description to demonstrate that Applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F. 3d 1559, 43, USPQ2d 1398.

8. Claims 1, 3, 6-15, and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one

skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the specification provides insufficient guidance for how to make and use the antibodies as broadly claimed.

The specification disclosure is insufficient to enable one skilled in the art to practice the invention as claimed without an undue amount of experimentation. Undue experimentation must be considered in light of factors including: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill in the art, the level of predictability of the art, the amount of direction provided by the inventor, the existence of working examples, and the quantity of experimentation needed to make or use the invention, see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) states, "The amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art." "The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling" (MPEP 2164.03). The MPEP further states that physiological activity can be considered inherently unpredictable. With these teachings in mind, an enabling disclosure, commensurate in scope with the breadth of the claimed invention, is required.

With regards to the instant claims, their breadth comprises a primary issue as regards the unpredictability of the claimed antibodies. Claim 1 is drawn to antibodies that bind to a drug of abuse that comprise a particular heavy chain variable region amino acid sequence. Therefore the claims encompasses antibodies that comprise only a heavy chain in the absence of a light chain, that bind to a drug of abuse. However, it is known in the art that the surface of the antibody molecule formed by the juxtaposition of the CDRs of heavy and light chains forms the

site to which antigens bind (see Janeway and Travers. Pg. 3:8). Therefore, it is unclear how an antibody that comprises only a heavy chain variable region, in the absence of a light chain, could bind to an antigen. Therefore, one of skill in the art is not enabled to make antibodies comprising only the heavy chains of claim 1 that bind to a "drug of abuse", as broadly claimed.

Additionally, it is noted that claims 20 encompasses using the claimed antibodies to treat addiction to a drug of abuse. However, the heavy chain variable regions of the instant claims are all derived from amphetamine specific antibodies. While it might be possible to treat amphetamine addiction with an amphetamine specific antibody, it is not clear how said antibody could be used to treat other drug addictions. Said antibody would not be expected to bind cocaine, and hence it is not clear how the antibody would be useful for treating cocaine addiction, for example. Furthermore, the instant specification does not provide any examples of using any antibodies to treat any type of drug addiction. Therefore, given the state of the prior art and the lack of guidance provided by the instant specification, the specification does not enable one of skill in the art to make or use the antibodies as broadly claimed.

9. No claim is allowed. The heavy chain sequences recited in Claim 1 are free of the prior art.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
Patent Examiner
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July 20, 2006

8/2/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER